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10/633,726	08/04/2003	Lee Weng	THERUS.007C1	5582

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EXAMINER	
FERNANDEZ, KATHERINE L	

ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
06/19/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

**Application No.**

10/633,726

**Applicant(s)**

WENG ET AL.

**Examiner**

Katherine L. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:11/25/2005,10/13/2005,7/21/2005.

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1. The application has been forwarded to the examiner by the 3700 SPRE Shop (via SPRE Henry C. Yuen) to construe the petitions filed October 2, 2006 as a request for reconsideration. Upon review and consideration, prosecution is reopened. The amendment after final filed on 10/2/06 has been entered. A new Office action follows.

***Response to Arguments***

2. Applicant's arguments filed October 2, 2006 concerning claims 10-14 have been fully considered but they are not persuasive.

After further consideration of the applicant's arguments on claim 10, examiner respectfully disagrees. Examiner would like to point out that "arresting bleeding" would cause an interruption in blood flow, thus decreasing the blood supply to the area being treated. Applicant further argues that "stopping blood flow from a ruptured vessel may in fact increase blood flow." However, as anticipated by Vaezy et al. in the abstract, lines 17-20, stopping blood flow would interrupt the supply of nutrients and oxygen to a region, such as a tumor (i.e. uterine fibroid tumor). It is inherent that nutrients and oxygen are carried by blood, thus causing an interruption in the supply of these elements means that the blood supply to the region is decreased.

With regards to claims 11-14, examiner would like to point out that Chapelon et al. disclose that cavitation waves are delivered to the target tissue producing a cavitation effect on the tissues being treated in column 7, lines 35-42). As stated in the previous action, the transmission path of the HIFU does cross the surrounding region, and therefore the ultrasonic waves are capable of causing necrosis of a substantial portion of tissue between the transducer and the transducer's focal point

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Therefore, with regards to claims 10-14, examiner maintains the previous office action dated August 1, 2006 and repeated below.

3. Applicant's arguments, see pg. 7, 2<sup>nd</sup> paragraph, filed 10/2/2006, with respect to the rejection(s) of claim(s) 15-17 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference, Fujimoto (US Patent No. 5,643,179), and is further discussed below.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by **Vaezy et al** '867 (US 6,425,867).

Vaezy et al. '867 teach a method of ultrasonically cutting off the blood supply to a uterine fibroid, comprising the following steps of: a) providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)), b) pre-selecting one or more tissue treatment sites located on the uterine fibroid whereby necrosing the tissues at the one or more tissue treatment site will decrease the blood supply to the uterine

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fibroid (see col. 16, lines 19-20; referring to treatment of fibroid and col. 16, lines 50-58; referring to necrosing tissue at a plurality of selected locations by causing lesions to the blood vessels).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 11, 13, and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over ***Vaezy et al*** '867 in view of ***Chapelon et al*** '526(US 5,601,526).

Vaezy et al '867 teach an efficient heating method using high intensity ultrasound energy comprising the following steps: providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)); and determining a tissue treatment zone (an indicated in Figure 6, and col. 16, lines 50-58, there is a treatment zone of one or more 112a lesion areas). Vaezy et al '867 do not teach energizing the ultrasound transducer to cause pre-focal heating at the tissue treatment zone and re-energizing the ultrasound transducer to cause necrosis at the tissue treatment zone. In the same field of endeavor, Chapelon et al '526 teach energizing the ultrasound transducer to cause pre-focal heating at the tissue treatment zone and re-energizing the ultrasound transducer to cause necrosis at the tissue treatment zone (see col. 7, lines 17-55 and col. 10, lines 35-63; referring to pre-heating of the area of interest with

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thermal waves and subsequent treatment at the focal region with focal cavitation waves in order to necrose the tissue).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have modified Vaezy et al '867 and incorporated the teachings of Chapelon et al '526 in the treatment of fibroids because as taught by Chapelon et al '526 this lowers the cavitation threshold providing a more effective treatment at a localized area of interest by limiting the treatment duration and avoiding spreading of the heat (see col. 5, lines 59-65 and col. 10, lines 35-43).

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Vaezy et al** in view of **Chapelon et al** '526 as applied to claim 11 above, and further in view of **Ribault et al** (US 6,488,639).

Vaezy et al '867 in view of Chapelon et al '526 teach all the steps as enumerated above except for the explicit recitation that pre-focal heating of the tissues causes temperature of the tissue to increase to about 50 degrees C. Ribault et al '639 teach that hyperthermia or heating of the tissues other than HIFU is performed at about 45 degrees C, which is about 50 degrees C as disclosed by the current invention (see col. 1, lines 17-30).

Therefore, it would have been obvious to one skilled in the art at the time that the invention was made that the hyperthermia temperature is about 50 degrees C as expressly stated by Ribault et al '639.

9. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vaezy et al** '867 in view of **Fujimoto** (US 5,643,179).



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Vaezy et al '867 substantially disclose all claimed features in claims 15-17.

Vaezy et al '867 teach a method of ultrasonically cutting off the blood supply to a uterine fibroid, comprising the following steps of: a) providing an ultrasonic transducer configured to emit focused high intensity ultrasound energy (see col. 16, lines 19-26; referring to use of high intensity focused ultrasound (HIFU)), b) pre-selecting one or more tissue treatment sites located on the uterine fibroid whereby necrosing the tissues at the one or more tissue treatment site will decrease the blood supply to the uterine fibroid (see col. 16, lines 19-20; referring to treatment of fibroid and col. 16, lines 50-58; referring to necrosing tissue at a plurality of selected locations by causing lesions to the blood vessels). However, Vaezy et al '867 do not disclose that the HIFU is being applied in angles around the circumference of the uterine fibroid. Fujimoto '179 discloses an ultrasonic medical treatment apparatus for applying a medical treatment to a tumor and the like within a living body by using ultrasonic waves (column 1, lines 8-12). The focal point (5) is scanned thoroughly over the entire diseased portion (4) by controlling the mechanical arm (10) from the control circuit (11) (see Figure 1, column 4, lines 22-34). As can be seen from Figure 3, the ultrasound beams are applied to the diseased portion's (4) base from a plurality of angles around the circumference of the diseased portion so that the entire diseased portion would be heated. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have Vaezy et al '867's HIFU transmission applied in angles around the circumference of the uterine fibroid. The motivation for doing so would have been to provide a controlled, non-



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invasive method for treating diseased areas of the body, as taught by Fujimoto '179 (column 2, line 47 through column 3, line 11).

**Conclusion**

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
ELENI MANTIS MERCADER  
SUPERVISORY PATENT EXAMINER